Summary of Safety and Effectiveness
Alumina V40™ Head

Submission Information

Name and Address of the Sponsor Of the 510(k) Submission	Howmedica Osteonics Corp 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Karen Ariemma Regulatory Affairs Specialist
Date of Summary Preparation:	October 20, 2000

Device Identification:

Proprietary Name:	Alumina V40™ Head
Common Name:	Femoral Bearing Head
Classification Name and Reference	Hip Joint, Metal/Ceramic/Polymer, Semi-Constrained, Cemented or Nonporous Uncemented Prosthesis, 21 CFR §888.3353

Predicate Device Identification

The Alumina V40™ Head is substantially equivalent to the Osteonics C-Taper Heads which were determined substantially equivalent via 510(k)s K971409 and K991952.

Device Description

Alumina V40™ Heads are ceramic femoral bearing heads that have been designed for assembly, through a taper lock mechanism, to titanium alloy femoral stems with a Howmedica Osteonics' V40™ trunnion design. The line extension adds V40™ Alumina Heads: 28mm and 32 mm diameter with –4mm, 0mm and +4mm neck offsets, and 36 mm diameter with –5mm, 0mm and +5 mm neck offsets. The modified heads are identical to the unmodified heads in every aspect with the exception of the starting diameter of the taper angle, which is smaller. The subject device is identical in material to the predicate device.

Intended Use

The V40™ Alumina Heads are single-use devices and may be used with any appropriately selected legally marketed Howmedica Osteonics' titanium alloy femoral stem that incorporates a V40™ trunnion. The V40™ Alumina Heads are intended for use with any appropriately selected

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2000

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corp
59 Routh 17
Allendale, New Jersey 07401

Re: K003413
Trade Name: Alumina V40 Head
Regulatory Class: II
Product Code: LZO
Dated: November 1, 2000
Received: November 2, 2000

Dear Ms. Karen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 003413

Device Name: Alumina V40™ Heads

Indications For Use:

The indications for use of the subject device, in keeping with those of other legally marketed Howmedica Osteonics' ceramic femoral bearing heads are as follows:

For Use as a Total Hip Replacement:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage vascular necrosis.
- Revision of previous cup arthroplasty or other procedures
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

For Use as a Bipolar Hip Replacement

- Femoral head/neck fractures or non-unions.
- Asceptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological considerations or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative Devices

510(k) Number K003413